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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,911	10/13/2000	Rostyslav Stoika	CEDAR-44649	9562

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EXAMINER
LI, QIAN J

ART UNIT	PAPER NUMBER
1632	10

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/687,911	Applicant(s) STOIKA ET AL.	
	Examiner Janice Li	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-53* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action* .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S. C. 121:

I. Claims 1-3, 5, 6, 9, and 52 are directed to a method of inhibiting the activation of a mammalian T-lymphocyte comprising delivering a PTTG-specific antisense oligonucleotide to the T-lymphocyte. Classified in Class 435, subclass 69.1, and Class 514, subclass 44.

II. Claims 1, 3-8, and 11-20 are directed to a method of inhibiting the activation of a mammalian T-lymphocyte comprising delivering a polynucleotide encoding PTTG carboxy-terminal-related polypeptide complexed with a cellular uptake-enhancing agent to the T-lymphocyte. Classified in Class 435, subclass 69.1, and in Class 514, subclass 44.

III. Claims 1, 3, 4-8, and 10 are directed to a method of inhibiting the activation of a mammalian T-lymphocyte comprising delivering a PTTG carboxy-terminal-related polynucleotide complexed with a cellular uptake-enhancing agent to the T-lymphocyte, wherein the polynucleotide is a peptide nucleic acid. Classified in Class 435, subclass 69.1, and in Class 514, subclass 44.

IV. Claims 1, 21-31, and 32-34 are directed to a method of inhibiting the activation of a mammalian T-lymphocyte comprising delivering a PTTG carboxy-terminal-related peptide or functional fragment thereof complexed with a cellular uptake-enhancing

agent to the T-lymphocyte. Classified in Class 435, subclass 69.1, and in Class 514, subclass 44.

V. Claims 35 and 53 are drawn to an *in vitro* screening method. Classified in class 435, subclass 6.

VI. Claims 36-40, and 43-51 are drawn to a composition comprising a tamed HIV vector operatively linked to a polynucleotide encoding PTTG carboxy-terminal-related polypeptide, and kits comprising the vector. Classified in class 536, subclass 23.1.

VII. Claims 36 and 41 are drawn to a composition comprising an antisense oligonucleotide. Classified in class 536, subclass 24.5.

VIII. Claims 36 and 42 are drawn to a composition comprising a peptide nucleic acid. Classified in class 536, subclass 24.2.

2. The inventions are distinct, each from the other because of the following reasons.

Inventions II-V and I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, each of the groups I-IV are drawn to a method of using antisense oligonucleotide specific for certain region of PTTG gene, using polynucleotide expressing PTTG gene, using a PTTG associated peptide nucleic acid, and using a PTTG polypeptide. Group V is drawn to in vitro screening methods. Each of these groups differs either in method steps or in material used in the method. The different methods use material different substances, have different method steps, different modes of operation, and have distinct technical considerations, and search criteria.

Inventions VI, VII, and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, each of the groups VI-VIII are drawn to a different product, i.e. antisense oligonucleotides design to target certain region of PTTG gene, polynucleotides expressing PTTG, peptides, and peptide nucleic acids. The different products are distinct in chemical structure and biological functions as well as modes of operation when used as therapeutic and diagnostic agents. Further, they can be used by materially different methods, such as used for a therapeutic composition or in a diagnostic kit.

The differences of the Inventions I-XII are further underscored by their divergent classification and independent search criteria.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search criteria, it would impose an undue burden to the Office if all the groups are examined together, thus, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention: Invention groups I is directed to a method of delivery antisense oligonucleotide, which binds to different regulatory region. If one of the groups I or II is elected, further election of a species, drawn to targeting a specific region of PTTG, is necessary.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1,-3, 5, 9, and 52 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

QJL
July 26, 2002

JAMES KETTER
PRIMARY EXAMINER